

510(k) SUMMARY

THIS SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION IS BEING SUBMITTED IN ACCORDANCE WITH THE REQUIREMENTS OF THE SAFE MEDICAL DEVICE ACT OF 1990.

510(k) Summary of Safety and Effectiveness
Certi*Cool Instant Cold Compress

K 960624

MAY - 6 1996

Submitted by: Certified Safety Manufacturing, Inc.
1400 Chestnut
Kansas City, MO. 64127
(816) 483-9090
Fax (816)-483-9091

Contact: Howard Gerson, Vice President
Date Prepared: February 8, 1996
Trade Name: Certi*Cool Instant Cold Compress
Common Name: Disposable Cold Pack

Classification Name: Disposable Cold Packs are classified as Class I medical devices, and are listed in 21 CFR 890.5710 as cold disposable pack.

The Certi*Cool Instant Cold Compress is substantially equivalent in design, composition and function to other disposable cold packs on the marketplace that employ a chemical reaction to produce cold. It is also substantially equivalent to our Edcool and Edcool J. Instant Cold Packs which were found SE by FDA on March 25, 1987 and assigned #K871006.

The Certi*Cool Instant Cold Compress is a self contained disposable unit that provides temporary cold therapy for body surfaces. Each unit is labeled with instructions for use as well as specific warning statements. Our product consists of an inner plastic pouch containing a green-colored water and an outer pouch containing ammonium nitrate. To activate the product, simply rupture the inner pouch by using an external force, such as a fist. Then, as the two ingredients mix, a chemical reaction results by producing temperatures below 40°F for a minimum of 15 minutes. These are single use devices.